ROSENTHAL, MONHAIT, GROSS & GODDESS, P. A.
ATTORNEYS AT LAW
SUITE 1401, 919 MARKET STREET
P. O. BOX 1070
WILMINGTON, DELAWARE 19899-1070

TELEPHONE (302) 656-4433
FACSIMILE (302) 658-7567
E-MAIL RMGG@RMGGLAW.COM

JOSEPH A. ROSENTHAL
NORMAN M. MONHAIT
KEVIN GROSS
JEFFREY S. GODDESS
CARMELLA P. KEENER
EDWARD B. ROSENTHAL
JESSICA ZELDIN

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VIA ELECTRONIC FILING/HAND DELIVERY

The Hon. Kent A. Jordan
J. Caleb Boggs Federal Building
844 N. King Street
Room 6325
Lockbox 10
Wilmington, DE 19801

RE: *In re Tricor Direct Purchaser Antitrust Litig.*, C.A. No. 05-340 (KAJ).

Dear Judge Jordan:

In accordance with D. Del. LR 7.1.2(c), I write on behalf of Direct Purchaser Plaintiffs to present the Court with new authority relating to issues addressed in Direct Purchaser Plaintiffs' and Defendants' briefing regarding Defendants' Motion to Dismiss. In those briefs, the parties cited and argued extensively concerning the lessons to be drawn from prior versions of Professor Hovenkamp's treatises discussing the application of the antitrust laws to cases involving product switches -- such as occurred in this case.[1]

Shortly after Defendants filed their Reply Brief, Professor Hovenkamp, *et al.*, published the 2006 Supplement to the treatise *IP and Antitrust: An Analysis of Antitrust Principles Applied*

[1] See, e.g., Defendants' Consolidated Opening Brief in Support of their Consolidated Motion to Dismiss Plaintiffs' Complaints (D.I. 39) at 10; Direct Purchaser Plaintiffs' Answering Brief in Opposition to Defendants' Consolidated Motion to Dismiss (D.I. 62) at 28; Defendants' Consolidated Reply Brief in Support of their Consolidated Motion to Dismiss Plaintiffs' Complaints (D.I. 69) at 13.

to Intellectual Property Law ("*IP and Antitrust*"). New Section 12.5 of the 2006 Supplement, entitled "Product Changes in the Context of FDA Approval," discusses product changes such as those at issue in this case, which Professor Hovenkamp calls "product hopping," and concludes that they can be unlawfully exclusionary under Section 2 of the Sherman Act.[2]

This new treatise Supplement concludes that a product change "could qualify as a predatory product change if it lacks substantial medical benefits." *See* Exhibit "A". Moreover, Defendants here strenuously argued in their reply brief that product changes were appropriately analyzed under the standards set forth in §12.2 of the Hovenkamp treatise, rather than those set forth in §12.3 as asserted by Plaintiffs. *See* Defs' Reply Br. at 13. The new Supplement expressly provides that pharmaceutical product changes are properly analyzed "[u]nder the analysis we offer in ***§12.3e3***". *See id.* (emphasis added).

Thank you for your consideration of this matter.

Respectfully submitted,

Jeffrey S. Goddess (Del. Bar No. 630)
jgoddess@rmgglaw.com

[2] A copy of Section 12.5 from the 2006 Supplement is attached hereto as Exhibit "A".

JSG/cmw
cc: (All via e-mail)
Mary B. Graham, Esquire
William F. Cavanaugh, Esquire
Chad J. Peterman, Esquire
Frederick L. Cottrell, III, Esquire
Anne Shea Gaza, Esquire
Steven S. Sunshine, Esquire
Maggie DiMoscato, Esquire
Elizabeth M. McGeever, Esquire
Scott E. Perwin, Esquire
Joseph T. Lukens, Esquire
Bruce E. Gerstein, Esquire
Barry S. Taus, Esquire
Adam M. Steinfeld, Esquire

EXHIBIT A

Herbert Hovenkamp
Ben V. & Dorothy Willie Professor of Law
University of Iowa

Mark D. Janis
Professor of Law and H. Blair and Joan V. White Intellectual Property Law Scholar
University of Iowa

Mark A. Lemley
William H. Neukom Professor of Law
Stanford University

Volume II

IP and Antitrust

An Analysis of Antitrust Principles Applied to Intellectual Property Law

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111 Eighth Avenue, New York, NY 10011
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2006 SUPPLEMENT

the listing of information in the Orange Book and by limiting patentees to a single 30-month stay for any given drug, regardless of the number of patents listed as covering that drug.[31] The result is that while antitrust challenges to past evergreening efforts will continue, there are unlikely to be new cases brought on the basis of continuing conduct.

§12.5 Product Changes in the Context of FDA Approval

Pharmaceutical patent owners have engaged in a second form of evergreening, one that might be described as "product-hopping." Product-hopping pharmaceutical companies faced with the possibility of generic competition once a patent expires or is held invalid sometimes make trivial alterations to their approved drugs, get FDA approval for those trivial alterations, and then replace the old product with the new product. For example, a patentee might switch from selling a drug in capsule form to selling the same formulation of the same drug in tablet form. While the change won't matter much to consumers, it can be sufficient to require a generic company to start the ANDA filing process over from scratch, delaying the date of generic entry and triggering an entirely new round of patent litigation. Because the patented pharmaceutical is now being sold only in the new tablet formulation, the generic company will be unable to rely on generic substitution to sell its ANDA-approved capsules. A number of antitrust challenges to product-hopping are pending as of this writing.

A pharmaceutical patent owner has no legal duty either to help its generic competitors or to continue selling a particular product. Patent owners may argue with some justification, therefore, that they cannot be held liable for stopping the sale of a product. At the same time, product-hopping seems clearly to be an effort to game the rather intricate FDA rules to anticompetitive effect. The patentee is making a product change with no technological benefit solely in order to delay competition. Under the

31. 21 U.S.C. §355(j)(5)(b).

analysis we offer in section 12.3e3, such a change could qualify as a predatory product change if it lacks substantial medical benefits.

The product-hopping problem could be solved if the FDA Act permitted generic substitution across formulations. In the absence of such a statutory change, antitrust cases will continue to arise.